

**Comments for consideration at FDA Regulation of OTC Drug Products Hearing
Docket No. 00N-1256**

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ReProtect is a small pharmaceutical company developing a spermicidal microbicide gel intended to protect women from pregnancy, HIV, and other sexually transmitted diseases. We thank the FDA for establishing the Microbicide Working Group to streamline the process of microbicide review. However, like other members of the microbicide development community, we were surprised and concerned by FDA staff at the January 2000 NIAID Preclinical Microbicide Workshop, when they suggested that all new spermicide/microbicide products would be classified as prescription drugs.

Our product, BufferGel, is made entirely with components that have been used mucosally for decades, and are generally recognized as safe (GRAS). BufferGel maintains a protective vaginal acidity by maintaining a safe and effective concentration of protons. The buffering agent in BufferGel is Carbopol®, a and gel-forming polymer that is used simply as an excipient in over 120 currently marketed pharmaceuticals, including at least 9 products used vaginally. Phase I studies show that, unlike most existing spermicides based on detergents, intensive use of BufferGel does not disrupt the cervicovaginal epithelium, and in this important respect, appears to be safer than detergent-based spermicides that have long been available OTC.

Other sponsors are developing microbicide products that have a similarly high expectation of safety. We believe that BufferGel and other microbicides based on non-toxic, non-absorbable, and non-systemic agents, should be directly approvable for OTC use after adequate preclinical and clinical testing and with appropriate postmarketing surveillance.

We believe the public health impact of vaginal microbicides would be severely limited if they were restricted to Rx status, since a woman is much less likely to use a microbicide if she must visit a physician to get a prescription. This is especially true for the very women who would most benefit from microbicides: the poor, the disadvantaged, and the young. Many women are unable, or too embarrassed or intimidated, to obtain safer-sex products from a physician.

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Moreover, sexually transmitted diseases and AIDS remain highly stigmatized in our society, and asking a doctor for a safer-sex product means telling the physician she intends to engage in high risk sex. Many women may wish to avoid such a conversation.

The argument might be made that hormonal contraceptives are widely used despite Rx classification, hence Rx status is not a severe barrier. This is an inappropriate analogy when applied to microbicides. Women understand and accept that they are at risk of pregnancy, and being a fertile woman carries no stigma. In contrast, a woman who seeks to obtain a microbicide must overcome a powerful stigma – she must reveal to others that she is having sex with an unsafe partner. In this setting, if the FDA erects an Rx hurdle for microbicides, the public health benefits are likely to be severely reduced.

We recognize that Rx-only status may enhance detection of certain adverse effects of new products that were not detected during clinical trials. We believe this might be an appropriate basis for Rx classification of some of the new microbicides now being developed. We believe that in its deliberations on the OTC vs. Rx status of vaginal microbicides, the FDA should consider not only the *benefit* of detecting adverse events in users of a new product, but also the *risk* to public health if the promise of these products undermined by an Rx hurdle. We ask the panel to consider the probable impact on public health if condoms were available only by prescription. Recall that condom sales increased substantially with the simple change of placing them on accessible displays rather than keeping them out of sight behind the pharmacist's counter (personal communication, Carol Carrozza, Director of Marketing, Ansell Healthcare Products Inc., 5/29/00). This marketing experience shows that even a *minor* barrier to access significantly limited the use of condoms. We believe that an Rx hurdle placed in the way of microbicides would much more dramatically limit the use of microbicides by women.

We urge the panel to proceed on a case by case basis with microbicides, and not establish a categorical guideline that new microbicide/spermicides will initially be classified as prescription drugs. Some new microbicides are designed with, and composed of, non-toxic ingredients with long track-records of safe mucosal applications. Categorically imposing an Rx hurdle would risk the loss of major public health benefits, especially for those women most in need of vaginal products for safer sex.